

DETAILED ACTION

Applicants' arguments filed on July 18, 2011, have been fully considered. Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Amendment to the claims filed July 18, 2011 has been entered. New claim 19-22 are under consideration.

Claims

Claim Rejections - 35 USC § 103 – Obviousness

1) Claims 15 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (US 5,618,840) as evidenced by Shapiro et al. (Oral Microbiology and Immunology, 1994) in view of Kunz et al. (US 2002/0169138). The rejection is maintained and applied to claims 19 and 22.

Rejection

Wright teaches antibacterial oil-in-water emulsions (title). The emulsions are stable when heated or exposed to significant levels of acid and base (column 2, lines 56-57). The emulsions can be used in pharmaceutical preparations, made up of an antibacterial emulsion and a pharmaceutically acceptable carrier (column 2, lines 58-65). Said preparations can be applied to oral surfaces, for example, as a mouthwash (column 3, lines 1-5). Oils useful in forming oily discontinuous phase of said emulsions include vegetable oils, such as soybean oil, canola oil, glycerol esters, flavor oils, such as peppermint oil, and mixtures thereof (column 2, lines 19-22). Peppermint oil is an essential oil that has anti-bacterial properties against bacteria in the oral cavity as evidenced by Shapiro et al. (Abstract) and therefore encompasses the limitation of an anti-bacteric substance in the oil phase. The compositions include cetylpyridinium chloride (a water soluble antiseptic substance encompassing an anti-bacteric in the water phase) (column 2, lines 29-32). The amounts of oil phase to water phase range from 1:4 to 1:2 on a volume to volume basis (column 4, lines 35-38).

Wright is silent about the visual appearance of the emulsions and the oils include aliphatic hydrocarbons, esters, alcohols and ethers.

Kunz et al. disclose delivery vehicles for bioactive agents and is used to disclose oils used in oil-in-water emulsions, encompassing claim 18. The compositions may be delivered orally (paragraph 0132). The vehicles include emulsions such as oil-in-water emulsions (paragraph 0116). The oils include vegetable oils, mineral oils, aromatic hydrocarbons, oils having animal origins, aliphatic hydrocarbons, aliphatic alcohols,

triglycerides, and hydrocarbons comprising esters and ethers (paragraphs 0045-0054).

The oils may also be used in mixtures (paragraph 0109). When the emulsions are diluted with water, they become cloudy (paragraph 0113) encompassing instant claim 15.

The reference differs from the instant claims insofar as it does not disclose the phase in which the active is dissolved or water soluble actives.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used the oils such as mineral oils, aromatic oils, aliphatic hydrocarbons, triglycerides, hydrocarbons comprising esters and ethers in mixtures in the oil phase in addition to those, such as peppermint oil, disclosed by Wright when formulating an oil-in-water mouthwash motivated by the desire to use oils suitable for use in the oil phase of oil-in-water emulsions as disclosed by Kunz et al. and supported by MPEP 2144.07.

As far as visual appearance is concerned, one skilled in the art would reasonably expect a formulation comprising oil and water phases combined in amounts described by the primary reference, encompassing those amounts recited by the instant claims, to be opaque. The disclosure of Kunz et al. further supports this reasoning by disclosing the addition of water causes the concentrated oil and water emulsions to become cloudy.

The prior art does not disclose the exact claimed values of 60% to about 95% aqueous phase and about 5% to 40% oil phase, but does overlap disclosing the oil and water phases in a 1:4 to 1:2 ratio: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Accordingly, since an overlap plainly exists here, it would have been obvious to have selected values within the overlap, consistent with the reasoning of the Peterson decision.

Response to Arguments

Applicant's Arguments

Applicant has amended the claims to replace the term "comprising" with the term "consisting". Thus the presence of essential oils is excluded from the compositions of the instant claims. Shapiro discloses essential oils and the essential oils are different from the vegetal oils, mineral oils and aliphatic oils recited by the instant claims. Shapiro only teaches the use of essential oils. Applicant's oils do not have any bacteric function. The Wright reference lacks any teaching that would cause a skilled worker in the art to combine that reference with Shapiro, Kunz or Pianotti. Cetylpyridinium chloride is included in compositions of the Wright and the instant claims also exclude cetylpyridinium chloride from being in the oil phase. Kunz does not disclose a mouthwash that adheres to the oral mucosa, it discloses a composition that is ingested

and is for continuously transporting a bioactive agent through a biologic membrane. It also does not teach antibacterial or disinfecting agents.

Examiner's Response

The Examiner asserts that Shapiro was used as evidence to support the properties of peppermint and is not used as a basis for the rejection. Wright is the primary references and discloses the oils recited by the instant claims. One would be motivated to combine the teaching of Kunz with the teachings of Wright because the both references teach oil in water emulsions and suitable oils used in oil in water emulsions. Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. Thus one would use the oils disclosed by Kunz in the composition of Wright because they are suitable for use in an oil in water emulsion. In regard to cetylpyridinium chloride (CPC) being excluded from the oil phase, one would reasonably conclude that CPC would also be included in the aqueous phase because, as Applicant asserts in the arguments (page 6, last paragraph), it is also water soluble. It is also noted that CPC is an antiseptic agent and therefore is encompassed by the instant claims which recites "antiseptic substances dissolved in said oil phase". Kunz also discloses compositions that are orally acceptable whether they are used to rinse the oral cavity or are ingested. Thus the oils of Kunz are suitable to use in the oral compositions of Wright. Wright discloses antiseptic and anti-bacterial agents and therefore it is not necessary for Kunz to disclose these agents. Therefore the claims are

obvious over Wright in view of Kunz. In regard to the essential oils, some essential oils are also aromatic oils and therefore are encompassed by the instant claims. Further essential oils have antiseptic properties and therefore meet the limitation of antiseptic substances dissolved in the oil phase.

2) Claims 16 and 17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (US 5,618,840) as evidenced by Shapiro et al. (Oral Microbiology and Immunology, 1994) in view of Kunz et al. (US 2002/0169138), as applied to claims 15 and 18 above in further view of Pianotti (EP 0244363). The rejection is maintained and applied to claims 20 and 21.

Rejection

Wright as evidenced by Shapiro et al. view of Kunz et al. is discussed above and discloses the composition may be used as mouthwashes. The combination of references differs from the instant claims insofar as it does not disclose the component in the water soluble phase of the oil-in-water composition.

Pianotti teaches an oral preparation in the form of mouthwashes or rinses (Page 3, line 24). The vehicle (e.g. pharmaceutically acceptable carrier, as described by the primary reference) is a water-alcohol mixture, present in the mouthrinse in an amount from 70 to 99.9% (page 3, lines 27-28), which is within the range for the aqueous phase

recited by claim 15. Water soluble compounds that comprise said vehicle are inorganic fluoride salts (page 3, lines 53-54), saccharin (page 4, line 19), xylitol (page 4, line 16), as well as colorants (page 4, line 11), encompassing instant claims 16 and 17. Example 4 on pages 7 and 8 demonstrates a mouthrinse comprising ethanol, encompassing instant claim 17. Essential oils, also flavor oils, include thymol, eucalyptol, and menthol encompass aromatic oils.

The reference differs from the instant claims insofar as it does not disclose the compositions as emulsions and only discloses the aromatic oils as a component encompassed by the oil phase.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used the mouthwash composition comprising a water-alcohol mixture, fluoride, saccharine and xylitol as the aqueous pharmaceutical carrier when formulated into a mouthwash of Wright as evidenced by Shapiro et al. view of Kunz et al. motivated by the desire to use a vehicle known in the art as suitable for mouthwashes, as disclosed by Pianotti. See by MPEP 2144.07.

Response to Arguments

Applicant's Arguments

See Applicant's arguments in regard to Wright, Shapiro and Kunz. Applicant further argues that there is no motivation to combine Wright with Pianotti. Further Pianotti discloses essential oils. The mouthwashes of Pianotti and that of the instant claims operate in a very different manner. The mouthwash of the instant claims provides a film to the oral cavity and the compositions of Pianotti do not.

Examiner's Response

See Examiner's Response above in regard to Wright, Shapiro and Kunz. Pianotti was used for its disclosure of actives used in mouthwashes. It would have been obvious to use these actives in the compositions of Wright due to their suitability to treat the oral cavity. See MPEP 2144.07. Further the essential oils of Pianotti are also aromatic oils, which are recited by the instant claims and therefore these oils are not excluded from the compositions of the instant claims. The compositions of Wright in view of Kunz would be able to form a film in the oral cavity because of the presence of the mixture of oils and therefore it is not necessary for Pianotti to disclose this function, especially considering that Pianotti was used for its disclosure of actives suitable of oral use.

Claims 19-22 are rejected.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612